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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,770	01/16/2001	Fei Yang	DEX-0113	8352

26259 7590 10/03/2002

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/03/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/700,770	Applicant(s) YANG ET AL.	
	Examiner Christopher H Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9,12,13</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 6-4-02 (paper no. 11) is acknowledged and entered into the record.
2. The amendment filed 6-4-02 (paper no.11) newly added SEQ ID Nos: 2, 4, and 5 which were not presented in the claimed as originally filed, therefore, claims 1-6 are examined to the extent that they read on SEQ ID Nos: 3 and 6 only.

Information Disclosure Statement

3. The Information Disclosure Statements filed 4-11-02, 6-24-02, 6-13-02, and 9-3-02 (paper nos. 9,12, 13, and 14) are acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Withdrawn

4. The rejection of claims 1-6 under 35 USC 112, 2nd paragraph, as being indefinite is withdrawn in view of the amendments set forth by the applicant.
5. The rejection of claims 1-6 under 35 USC 102(b), as being anticipated by Cohen *et al* is withdrawn in view of the amendments set forth the applicant. It is noted that the rejection made under 35 USC 102(b) should have been a rejection made under 35 USC 102(e).

New Claim Rejections

Claim Rejections - 35 USC § 112

6. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of diagnosing the presence of lung cancer in patient tissue samples, does not reasonably provide enablement for methods

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of diagnosing metastatic lung cancer, staging lung cancer, monitoring for the onset of metastasis or monitoring changes in stages of lung cancer in any bodily fluid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or

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absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The nature of the invention: The claims of the instant invention are drawn to a method of diagnosing the presence of lung cancer, diagnosing metastatic lung cancer, staging lung cancer, monitoring lung cancer for the onset of metastasis, and monitoring for changes in stages of lung cancer in cells, tissue and bodily fluid.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that noninvasive techniques used in the determination of cancer staging are often limited. Lau *et al* (Chest Surg Clin N Am 2000 Nov ;10(4):781-801) teach that although the techniques used in the staging of cancer are useful, there are significant limitations in such techniques and that invasive surgery is the only clear indication of cancer staging.

The amount of direction or guidance present and the presence or absence of working examples: The working examples of the instant invention are drawn to a method of determining the expression or lack of expression of the LSG genes in cancerous cells and tissue versus normal cells and tissue, wherein the presence of expression correlated with the presence of cancer. However, the instant application has not disclosed to one of skill in the art how to determine metastasis, stage, monitor for onset of metastasis or monitor for changes in staging of lung cancer in any cells, tissues or any bodily fluids. The working examples of the instant invention only provide a positive or negative determination of lung cancer in cells and tissue, and does not provide to one of skill in the art the necessary data that would show how to determine metastasis,

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stage, monitor for onset of metastasis or monitor for changes in staging of lung cancer in cells, tissues or bodily fluid.

The breadth of the claims and the quantity of experimentation needed: Because the instant specification only provides a clear delineation between the presence or absence of cancer, and does not provide any qualitative analysis of determining metastasis, staging of lung cancer, monitoring for the onset of metastasis or monitoring for changes in the staging of lung cancer, and absent sufficient teachings in the specification to overcome the teachings of unpredictability found in the art, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Conclusion

No claim is allowed. Because of the new claim rejections, this action is made NON-FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
September 26, 2002

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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